

Application No. 10/521,298
August 13, 2008

REMARKS

Claims 1, 2, and 4 – 20 are currently pending. Claim 1 is the only independent claim. In the Office Action, the Examiner finally rejected all of the pending claims as allegedly anticipated by PCT Application WO 01/87329 to Papadimitriou. In addition, Claim 2 was rejected under Section 112, second paragraph as allegedly indefinite. Also, dependent Claims 10 – 12, 15, 19, and 20 were objected to as allegedly being of improper form and failing to further limit the claim from which they depend. Finally, Claims 1, 10 – 12, 15, 19, and 20 were rejected under Section 112, second paragraph, as allegedly indefinite.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Prior Art Rejections.

The Examiner has maintained the rejections of Claims 1-20 on the alleged basis that they are anticipated by Papadimitriou (WO 01/87329).

In their previous amendment, Applicants partially closed the claims using the “consisting essentially of” transition; however, the Examiner refused to give weight to this amendment, arguing instead from the MPEP that “[w]ith respect to the phrase ‘consisting essentially of’, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, ‘consisting essentially of’ will be construed as the equivalent of ‘comprising’.”

Since the Examiner refuses to afford proper weight to the “consisting essentially of” transition, Claim 1 is amended herein to use the closed “consisting of” transition. Thus, Claim 1 now calls for a stable pharmaceutical composition of erythropoietin (EPO) consisting of (a) a therapeutically effective amount of EPO, (b) a pharmaceutically acceptable pH buffering system, (c) a poloxamer polyol, (d) a polyhydric alcohol and, optionally, (e) an isotonifying agent.

Claim 1 as amended (and as amended previously) patentably distinguishes over Papadimitriou because Papadimitriou teaches the necessity of including an antioxidant such as methionine in any “stable” EPO composition. Applicants have found that an effective EPO composition can be provided without antioxidants. In this regard, Applicants contend that the

Application No. 10/521,298
August 13, 2008

claims sufficiently distinguish from the art using either of the transitions “consisting essentially of” or “consisting of.” The specific compositions disclosed on pages 22 and 23 of Papadimitriou include methionine as an antioxidant. Example 11 of the Papadimitriou reference likewise emphasizes the need to include antioxidants such as methionine in the composition. The Papadimitriou reference fails to suggest any antioxidant-free EPO composition according to Claim 1, or any of Applicants’ other claims.

It follows, then, that the Papadimitriou reference cannot lawfully be said to anticipate or render obvious the subject matter of Claim 1. Further, since the Papadimitriou reference fails to anticipate or render obvious Claim 1, it also fails to anticipate or render obvious any of claims 2 & 4 – 20, which depend from Claim 1.

II. The Indefiniteness Rejection of Claim 2.

The Examiner has also maintained his rejection of Claim 2 as allegedly indefinite. While Applicants disagree, Claim 2 is amended herein to remove the “substantially” language and to recite that the composition is free of serum albumins rather than “additives derived from human and/or animal origin, other than EPO” in order to advance prosecution of this case. It is respectfully submitted that this amendment overcomes any alleged ambiguity in the language of the claim, and that the indefiniteness rejection of Claim 2 should be withdrawn.

III. The 37 C.F.R. § 1.75(c) Objections

The Examiner also objects to defendant Claims 10-12, 15, 19, and 20 under 37 C.F.R. 1.75(c), alleging that they are not in proper defendant form because, in his view, the “comprising” transition used therein does not further limit the subject matter of Claim 1. Claim 1 used the transition “consisting essentially of” and, as previously noted, has now been further amended to use the transition “consisting of.” Again, Applicants disagree, but in order to advance prosecution, they have amended defendant Claims 10-12, 15, 19, and 20 to change the “comprising” form back to the original “is” form. In light of the foregoing, it is submitted that the Examiner’s objections are now moot and should be withdrawn.

Application No. 10/521,298
August 13, 2008

IV. The Indefiniteness Rejection of Claims 1, 10-12, 15, 19, and 20.

Finally, the Examiner rejected Claims 1, 10-12, 15, 19, and 20 alleging they are indefinite because the base Claim 1 was written using the “consisting essentially of” transition and the dependant claims were written using the “comprising,” transition. Again, although this rejection is not well taken, the parent Claim 1 has been amended to use the transition “consisting of” and dependent Claims 10-12, 15, 19, and 20 have been amended to change the “comprising” form back to the original “is” form. Accordingly, the Examiner’s grounds of rejection are now moot and the indefiniteness rejections should be withdrawn.

In light of the foregoing, the present amendments are believed to place the application in a condition for allowance and entry of the foregoing amendments and allowance of Claims 1, 2, and 4 – 20 is respectfully solicited.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,
LUEDEKA, NEELY & GRAHAM, P.C.
By: /Mark S. Graham/
Mark S. Graham
Registration No. 32,355

Date: August 13, 2008
P.O. Box 1871
Knoxville, Tennessee 37901
(865) 546-4305